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BEFORE THE COMMITTEE ON GOVERNMENT REFORM

**SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND
HUMAN RESOURCES**

UNITED STATES HOUSE OF REPRESENTATIVES

November 1, 2005

The regulatory system upon which Americans have relied for over 50 years to assure a safe and effective drug supply is broken, and is rapidly becoming irrelevant. The massive influx of counterfeit and substandard drugs has simply overwhelmed the regulators – and rendered current laws and regulations farcical.

I do not say this for shock value. It is simply true. Few observers are in a position to discuss this matter dispassionately. The regulators themselves, of course, need to defend their turf and to hew to Administration policy. Pharmaceutical companies are reluctant to criticize their own regulators or in today's environment, almost anyone in the government. And the counterfeiters are hardly likely to seek an opportunity to appear before this committee.

The collapse of the barriers against counterfeits has been on the horizon for many years, but only in the past five has it seriously breached the regulatory levees. The U.S. is being flooded with fake drugs as I speak. It is uncertain whether the system can be repaired, or whether it will have to be entirely abandoned. As in the case of New Orleans, once a portion of the levee collapses, the balance of the dikes, while undamaged, become little more than quaint relics.

Counterfeits in the U.S. Drug supply

There are three major sources for counterfeit prescription drugs in the U.S.: “personal” imports, Diversion and the Internet.ⁱ The size of the counterfeit problem from these sources is impossible to measure with precision, but the evidence is overwhelming that the amount of bogus drugs in this country vastly exceeds the rather modest estimates of only a few years ago.ⁱⁱ

- In 2004, the FDA, Office of Criminal Investigation initiated 58 counterfeit drug investigations. In 2000, they opened only 6 cases. Their resources have not changed much in that period, just their workload.
- In 2000, fewer than two dozen people were indicted for dealing in counterfeit drugs. *Just so far* in 2005, more than 200 indictments have been handed up.

- In 2000, seizures of fake pharmaceuticals accounted for fewer than 100,000 doses. By 2004, more than 3 *million* fake medications were seized.ⁱⁱⁱ
- Despite several high-profile busts in the past two years, Internet pharmacies have proliferated. More than 1000 sites offer prescription drugs *without a prescription or examination by a physician*.
- As Internet pharmacies have expanded, so has mail-order fulfillment of orders. Every day, over 100,000 packages arrive by U.S. mail from overseas pharmacies. Spot inspections of these shipments reveals that 88% if them are not in compliance with U.S. standards.^{iv}
- “Personal” imports of pharmaceuticals, especially from Mexico, are essentially unregulated by any governmental authority. Because of this, a lively *commercial* trade has developed along the border through which millions of doses of fake drugs enter the U.S. market.^v
- Terrorist threats to the U.S. pharmaceutical supply have been taken seriously by the FDA and terrorism experts. In several studies, counterfeit drugs were identified as a likely vehicle which could be used by terrorists to attack the United States.^{vi}

“Personal Imports”

U.S. drug regulations currently permit the importation of prescription pharmaceuticals for the personal use of the traveler.^{vii} These are nominally restricted to a 90-day supply. These restrictions are so seldom enforced, however, as to invite bulk importation of thousands of drugs purchased in Mexican Farmacias into the U.S. It is reliably estimated at up to 1/3 of these drugs are fakes.^{viii} Although the practice of “personal imports” has been touted as a money-saving alternative to high drug costs in the United States, it has served as a superhighway for criminals profiting from the maladies of America’s seniors.

Since 9/11, the Customs Service (CBP) has focused primarily on terrorist threats and controlled substance interdiction. Tourists carrying trunkfuls of prescription meds, however, are routinely waved through the border checkpoints. A considerable number of these “tourists” are in fact entrepreneurs who take ample advantage of the virtually non-existent enforcement to import huge caches of drugs which they distribute with impunity.

Diversion

Drug diversion is one of the principal methods by which counterfeits enter the legitimate market. The pharmaceutical supply chain is particularly vulnerable to this practice since it is not controlled or regulated by any single entity – private or governmental.

Unlike most products, manufacturers generally do not control drug distribution much beyond their loading docks. Drugs may go through a dozen or more middle-men’s hands before they are finally consumed by a patient. Drugs intended for certain markets, such as African AIDS sufferers, for example, are routinely re-routed back to the U.S. and sold for much higher prices by greedy and cynical market manipulators. Once the supply chain is breached in this manner, it is a simple matter to substitute fake products for the clandestinely diverted legitimate goods. In fact, *every single case* of counterfeit drugs investigated by the FDA in the past five

years where the fakes were found in legitimate pharmacies has involved diversion as an entry point.

In other cases, diverters exploit the weaknesses in the supply chain by inserting drugs which have been acquired by fraud or simply stolen. These drugs are often relabeled with fake packaging and sold to unwary customers. This, for example, is what happened in the famous Lipitor case in which more than 50 people have now been implicated. Thousands of Americans ingested (or injected) these fakes, unaware of the tampering, sometimes suffering life-threatening (or ending) consequences.^{ix}

While the government has arrested scores of people for this sort of activity, arrests to date represent a tiny fraction of the scams that are in play. Remember, these kinds of violations are not (or should not be) difficult to detect. The perpetrators are selling their goods in plain sight – not in some back alley. The problem is that the regulatory framework—and the resources necessary to make it work – are so antiquated and miniscule respectively as to make the law itself irrelevant.

It has been suggested that the diversion problem is being addressed by the wholesale distribution industry itself, as well as by improvements in state regulations. The problem, however, persists. The recent attention to the issue by the industry and state officials has resulted in a complex patchwork of regulations, self-imposed “standards” and conflicting laws. Ironically, this mosaic of rules has made the identification of counterfeit pharmaceuticals even more complex and difficult.

Internet

The growth of the Internet has spawned a new class of villain who preys on the weak and the vulnerable. Aside from the 17 or so Internet pharmacies certified by the VIPPS program, the vast majority of these are either highly questionable or downright criminal.^x

The studies which have been made of Internet “prescribing” and fulfillment of orders are virtually unanimous in concluding that this activity is rife with fraud and the wholesale delivery of substandard and counterfeit drugs. Companies such as ICG of Princeton, NJ, track these pharmacies on an around-the-clock basis and can attest to the sinister and altogether illegal activities which are the norm in this industry.

Generally, Internet pharmacies ship orders to their customers through the U.S. mail or through such companies as FedEx, UPS and others. They collect payment through the same types of credit cards most of us carry every day. None of these “choke points” for the delivery of counterfeit medicine has been used by the government to interdict fake drugs. This is not because they could not do so. The FDA, for example, has conducted spot checks of mail facilities, and found massive evasion of their regulations in almost every package.^{xi} There is no regulatory authority for the FDA or the CPB to merely return suspect packages to the sender, so millions of doses of potentially lethal drugs enter the U.S. under the very noses of law enforcement every day.

Remedial Measures

The choice facing the Congress in this matter is straightforward: either repair the obsolete laws and regulations that are failing, or abandon the pretense of protecting the American public from bogus drugs altogether. I certainly hope that the latter solution is not adopted, but it would be preferable to the charade of “enforcement” as it now exists.

What can be done? Several rather simple steps could be taken which would have an immense impact on the effectiveness of law enforcement to interdict counterfeit medications:

- Adopt “Pedigree” rules for Rx pharmaceuticals. The FDA proposed such rules more than ten years ago, but they *still* have not been adopted.^{xii} Pedigree rules would enable law enforcement, manufacturers and retailers to confirm that counterfeit drugs had not entered the supply chain. The absence of pedigrees for drugs has enabled unscrupulous wholesalers to substitute fakes for legitimate products with near impunity.
- Adopt federal minimum standards for drug wholesalers. Although the FDA has elaborate rules for prescribing drugs, there are few federal requirements as to who may handle prescription medications in the supply chain – this issue is almost totally a matter of state regulation. In some states, even convicted felons are permitted to distribute huge quantities of drugs with only minimal oversight.^{xiii} Rogue wholesalers have been largely responsible for the epidemic of counterfeit drugs entering the supply chain through the diversion “leaks” noted previously.
- Give the FDA power to require “prior approval” of drug repackagers to ensure that process does not compromise the quality of any drug. Drug repackagers should be subject to the same requirements regarding overt and covert counterfeit-resistant technologies as original manufacturers.
- Strictly enforce the PDMA restrictions on “personal use” imports.^{xiv}
- Specifically authorize the FDA and CBP to return suspect drugs to the sender if they are detected during the screening process that is already in place in international mail facilities. Repeal any requirement that each shipment be individually tested. This measure will effectively shut down rogue offshore Internet “pharmacies”, and is much more cost-effective than attempting to identify and prosecute the website operators.
- Require the CPB to notify the legitimate manufacturer within 5 days of a detention of suspected counterfeit drugs bearing their name or trademark.
- Grant the FDA Office of Criminal Investigation the authority to issue administrative subpoenas *at least* in drug or medical device counterfeiting investigations.^{xv}

- Permit the FDA Office of Criminal Investigations to retain seized assets of drug counterfeiters, smugglers and diverters. Currently, such asset seizures are routed to the Justice Department's Assets Forfeiture Fund or the Treasury's General Fund.
- Require more explicit manifest requirements – including precise descriptions – of products subject to FDA oversight. Currently, only the most general descriptions are required on Customs forms. Counterfeits routinely slip by CPB because their descriptions are so generic.
- Increase penalties for drug counterfeiting including making such activities a *specific* predicate for both civil and criminal RICO charges. Treat Rx drug counterfeiters no less harshly than those convicted of dealing in controlled substances by increasing the maximum penalty for drug counterfeiting to 20 years..
- Require that the FDA (rather than merely CPB) be instructed by the U.S. International Trade Commission to enforce ITC orders in affirmative Section 337 cases that involving articles (including drugs) which fall under the jurisdiction of the FDA.^{xvi}
- Apply the moiety provisions such as those of 19 U.S.C. § 1619 to drug counterfeiting cases whether or not the counterfeits were imported. This would expand the investigative reach of law enforcement almost overnight, without any net cost to the government.^{xvii}
- Reallocate resources within the FDA to bolster the law enforcement functions of the agency. The FDA spends more than 20 times as much money on inspecting legitimate suppliers than it does on investigating blatant criminal conduct. This is akin to ticketing jaywalkers while a bank robbery is occurring 10 feet away.

I appreciate your attention and will be pleased to expand upon any subject mentioned in my remarks.

ⁱ There are, of course, many counterfeit drugs offered on the black market and sold along with controlled substances. In these cases, however, consumers usually are aware that they are purchasing illicit substances. My remarks focus on counterfeit drugs sold to consumers who may have no reason to doubt that they are buying legitimate products.

ⁱⁱ In 2003, the World Health Organization and the FDA estimated that counterfeits made up 10% of the global medicines market and were present in both industrialized and developing nations. It was estimated that up to 25% of all medicines in developing countries are counterfeit or substandard. By last month (September) the WHO revised its estimates of counterfeit drugs in Europe *alone* to be 10% of the market – up from zero only a decade ago.

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ⁱⁱⁱ Source: EDDI, Inc. Includes both federal and state seizures in the United States.

^{iv} Statements of John M. Taylor III, Associate Commissioner for Regulatory Affairs, FDA before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, July 22, 2004 and Statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA before the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, Senate Committee on Commerce, Science and Transportation, September 5, 2001.

^v See e.g. Statement of Dr. Marv Shepard, College of Pharmacy, University of Texas before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, July 25, 2002 and other publications by Dr. Shepard.

^{vi} See, e.g. An Analysis of Terrorist Threats to America's Medicine Supply, Global Options, Inc. 2003. In that year, the FDA formed two Working Groups for the evaluation of Counterfeiting and Tampering vulnerabilities and security solutions for foods, pharmaceuticals and biological products (Product Surety Task Forces). These were composed of industry representatives, government officials, and experts in product track/trace and authentication technologies. Their reports were submitted to the FDA in 2004.

^{vii} The Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the interstate shipment of unapproved drugs including drugs approved in the U.S. but manufactured abroad. In general, it is legal for US residents to import medications from outside the US provided the following conditions are met:

- A) The product was purchased for personal use and does not exceed a 3 month supply.
 - B) The product is not for resale.
 - C) The intended use of the product is appropriately identified.
 - D) The patient seeking to import the product affirms in writing that it's for the patient's own use.
 - E) The patient provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product.
 - F) The medication is not a controlled substance, e.g. sleeping pills, Valium, narcotics. Etc.
- These restrictions are seldom, if ever enforced.

^{viii} See Note 4 Id.

^{ix} The actual number of victims is unknown. This is because the counterfeits are extremely difficult to track and detect. In most cases, the evidence has been destroyed by the customer by the simple act of taking the drug. In others, ill effects have gone undiagnosed since the patient was ill in the first place, and failure to recover is one of the predictable consequences of life-threatening diseases – medications or no. Counterfeits are not suspected as a cause until it is too late, and then it is often impossible to prove the link.

^x To be VIPPS (Verified Internet Pharmacy Practice Site) certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to National Association of Boards of Pharmacy compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

^{xi} See Note 3 *supra*

^{xii} In 1994, the FDA issued a proposed rule implementing the Prescription Drug Marketing Act (PDMA). In December, 1999 the Agency published final regulations in 21 CFR part 203 implementing the provisions of the PDMA. As of today, this rule has still not been implemented.

^{xiii} Michael Carlow, for example, had previously been convicted on two occasions for dealing in controlled substances and violating numerous statutes concerning drug wholesaling, , but was able to secure controlling interest in numerous licensed pharmaceutical wholesalers in Florida. Dozens of similar instances have been documented in the past five years which can be provided to the Committee Staff upon request.

^{xiv} See Note 5 *supra*.

^{xv} Administrative subpoenas may already be issued in cases involving Federal health care offenses (18 U.S.C. 3486), but these subpoena powers are not available to the very agency charged with enforcing the law (i.e. the FDA).

^{xvi} 19 U.S.C. 1337

^{xvii} A moiety concept might be combined with the *qui tam* provisions of 31 U.S.C. §§ 3729-3733 to induce disclosures from insiders when any counterfeit drugs are directly *or indirectly* supplied under any government program.